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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/730,236	12/08/2003	Robert Sixto JR.	ISD-056 C1	2523
36822 7590 10/15/2009 GORDON & JACOBSON, P.C. 60 LONG RIDGE ROAD SUITE 407 STAMFORD, CT 06902				
EXAMINER				
BLATT, ERIC D				
ART UNIT		PAPER NUMBER		
3734				
MAIL DATE		DELIVERY MODE		
10/15/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/730,236

Applicant(s)

SIXTO ET AL.

Examiner

Eric Blatt

Art Unit

3734

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 July 2009.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 12-26 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-10 and 12-26 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7-29-2009 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 19 recites "at least one of said plurality of retainer portions are located on each of said first and second arm portions." Firstly, since this language refers to *one* of the retainer portions, it should read that the retainer portion *is* located on each of said first and second arm portions. Secondly, it is unclear how a single retainer portion may be located on each of the first and second arm portions. For present purposes, this claim will be interpreted as though it reads, "at least one of said plurality retainer

portions is located on the first arm portion, and at least one of said plurality of retainer portions is located on the second arm portion."

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 9, 10, 12, 13, 17, 19 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by West (US 4,648,158).

West teaches a clip that is capable of being used for surgical purposes (Figures 1-3) comprising a bridge portion 10 connecting first and second arm portions. The first and second arm portions extend between the bridge portion 10 and retainers 12, 14 and 16. Two retainers 14 and 16 extend from the first arm in a direction parallel to the first arm and past the end of the second arm portion, and one retainer 12 extends from the second arm in a direction parallel to the second arm and past the end of the first arm portion. Each of the retainers has a tip that is capable of piercing tissue, and is adapted to be plastically deformed toward the arm to which it is not attached and adjacent the tip of the arm to which it is not attached. The first and second arm portions and the bridge portion are substantially stiff.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3, 4 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over West (US 4,648,158).

West discloses all elements of claims 3, 4 and 14-16 except for the clip being made from titanium (claims 3 and 14) or stainless steel (claims 4 and 15), and the retainer portion having a length substantially 0.7 to 2 times the dimension between an outside of the first arm portion and an outside of the second arm portion. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of West by forming the clip from titanium or stainless steel since these were well known materials that were used to prevent rusting and this modification would not have produced unexpected results. Additionally, it would have been obvious to one skilled in the art to modify the length of the retainer portion such that it has a length substantially 0.7 to 2 times the dimension between an outside of the first arm portion and an outside of the second arm portion since it has been held that where the general parameters of a device are known, determining an optimal range for the functionality of the device requires only routine skill in the art.

Claims 21-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over West (US 4,648,158) in view of Fogelberg et al. (US 5,833,700).

Regarding claims 21-26, West fails to disclose the claimed method wherein the clip is applied to tissue. Fogelberg discloses a structurally related clip and teaches that such clips may be applied to tissue to maintain said tissue in a compressed state. (See Abstract) Fogelberg teaches providing a clip applier that pre-compresses the tissue and applying the clip to said tissue to hold the tissue in the compressed state. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of West by using it in combination with a clip applier to compress tissue and hold said tissue in a compressed state for purposes such as occluding a blood vessel to prevent bleeding during a surgical procedure as taught by Fogelberg. So modified, the retainer attached to the second arm of West would be folded about (taken to mean near) the tip of the first arm.

Regarding claim 24, West does not disclose piercing the retainer through tissue. During the modified procedure, a target vessel may be embedded or muscle or connective tissue. Although the vessel may be removed from such tissue prior to clipping the vessel, some such tissue may remain. In order to clip the vessel, it would have been obvious to push the retainer around the vessel and through any surrounding tissue. This step would comprise piercing the retainer through tissue.

Regarding claim 25, Fogelburg teaches applying clips on blood vessels. It would have been obvious to apply the clip on other, non-tubular tissues since clipping non-tubular tissues was well known in the art at the clip of West would be capable of performing this function.

Regarding claim 26, West discloses plastically deformably bending the retainer, but does not specify through what angle this bend occurs. It appears from Figure 2 that the retainer is bent through an angle of approximately 180 degrees, but it is difficult to precisely determine the extend of the bend. It would have been obvious to one of ordinary skill in the art to bend the retainer through substantially 180 degrees in order to fully close the clip and maintain the enclosed tissue between the arms.

Claims 1-20 rejected under 35 U.S.C. 103(a) as being unpatentable over Golyakhovsky et al. (US 4,800,879) in view of Yi (US 5,409,499).

Regarding claims 1, 2, 4-13, 15, 16 and 21, Golyakhovsky discloses a clip comprising first and second arms 2, 1 respectively, and a bridge portion 3 that joins the first and second arms. There is a retainer 7 extending from second arm 1 comprising hook portions 14a. First arm comprises catch portions 14b. The clip has a configuration wherein the arms extend substantially parallel to one another and the retainer 7 extends longitudinally from the second arm 1, and another configuration wherein the retainer 7 is wrapped around the tip of the first arm 2 such that hook portions 14a engage the catch portions 14b. The clip, including the arms and the bridge portion comprise a substantially stiff plastic, and therefore, are substantially stiff. Examiner notes that bridge portion 3 defines a hinged joint, but holds that the joint may be considered substantially stiff since it comprises a substantially stiff material and has limited ability to elastically deform. Furthermore, bridge portion 3 allows movement along only one rotational dimension, and is substantially stiff in all other dimensions.

The tip of the first arm is capable of piercing tissue. Retainer 7 has a length substantially 0.7 to 2 times the dimension between an outside of the first arm and an outside of the second arm. (Figure 8) Alternatively, it would have been obvious to one skilled in the art to modify the length of the retainer since it has been held that where the general parameters of a device are known, determining an optimal range for the functionality of the device requires only routine skill in the art.

Golyakhovsky fails to disclose that the arms and bridge portion comprise a single continuous piece of material. Yi teaches a related clip (Figure 1) having arms that undergo a rotation during application similar to that of the Golyakhovsky clip, and teaches that the bridge portion may be formed as a living hinge 12 such that the arms and bridge portion comprise a single continuous piece of material. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Golyakhovsky by providing the bridge portion as a living hinge since this was a known alternative and the modification would not have produced unexpected results.

Regarding the recitation that the first and second arm portions and the bridge portion maintain a generally U-shaped configuration in which the first and second arm portions are substantially parallel to each other before during and after application of the clip to tissue of the patient, Examiner notes that the recited method steps—maintaining a U-shaped configuration before, during and after application of the clip to tissue of the patient—are interpreted as functional language since method steps may not be positively claimed in an apparatus claim. The modified clip of Golyakhovsky is capable of

maintaining a generally U-shaped configuration in which the first and second arm portions are substantially parallel to each other before during and after application of the clip to tissue of the patient. (When the arms are near each other, but not touching, they will be substantially parallel, and a thin portion of tissue may be placed between said arms so that the clip may be applied to said tissue.)

Regarding claims 3 and 14, Golyakhovsky does not disclose that the clip is made from a unitary piece of titanium or titanium alloy. Yi discloses that medical clips may be formed from titanium or titanium alloys. (Col. 3, Lines 50-60) It would have been obvious to one of ordinary skill in the art to make the clip of Golyakhovsky from titanium since it Yi teaches that titanium was known to be used for clip formation and its used would not have produced unexpected results.

Regarding claims 17-20, hook elements 14a are interpreted to define a plurality of retainers. Regarding claim 20, the claim does not require retainer portions that extend from the first arm. Since the retainer portions that extend from the second arm extend longitudinally beyond the first arm, the clip of Golyakhovsky meets the recited limitations of claim 20.

Response to Arguments

Applicant's arguments filed 9-28-2009 have been fully considered but they are not persuasive.

In the interview conducted July 7, 2009, Examiner indicated that the amendment reciting that first and second arm portions and the bridge portion maintain a generally U-

shaped configuration in which the first and second arm portions are substantially parallel to each other before, during, and after application of the clip to tissue of the patient would likely distinguish the claimed invention over the Golyakhovsky reference. Upon further consideration, however, Examiner notes that reciting the shape of the clip *before, during, and after application* renders these recitations functional, since method steps may not be positively recited in an apparatus claim. Since the modified Golyakhovsky device is capable of maintaining the claimed configuration during these steps, this recitation does not distinguish the claimed invention over the Golyakhovsky device.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric Blatt whose telephone number is (571)272-9735. The examiner can normally be reached on Monday-Friday, 9:00 AM-6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric Blatt/
Examiner, Art Unit 3734

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3734